PROGRAM GUIDELINES FOR PROJECT GRANTS FOR FAMILY PLANNING SERVICES

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of Public Health and Science
Office of Population Affairs

Table of Contents

PART I

1.0 Introduction to the Program Guidelines

This document, *Program Guidelines for Project Grants for Family Planning Services*, has been developed by a task force under the direction of The American College of Obstetricians and Gynecologists (ACOG) for the Bureau of Community Health Services, U.S. Department of Health and Human Services (DHHS), to assist current and prospective grantees in understanding and utilizing the Title X family planning services grants program. The document is organized into two parts. Part I (sections 1-6) covers project management and administration, including the grant application and award process. Part II (sections 7-11) covers required, recommended, and related client services and clinic management.

Reference is made throughout the document to specific sections of the Title X law and regulations, which are contained in their entirety in Attachments A and B. (Reference to specific sections of the regulations will appear in brackets, e.g., [45, CFR 74, Subpart H].) Federal sterilization regulations are contained in *Attachment C*. Reference is made throughout the document to selected other materials that provide additional guidance in specific areas. These materials are classified as *Appendices* or *Related Documents*. The *Appendices* contain program requirements relating to the operation of Title X projects and facilities. *Related Documents* contain relevant standards and protocols that represent current accepted medical practice. A current listing of these materials is attached to the document. Projects may contact the appropriate DHHS Regional Office listed in *Attachment D* for information on how to obtain them.

1.1 DEFINITIONS

Throughout this document, the words "shall" and "must" indicate *mandatory* program policy. "Should" indicates *recommended* program policy relating to components of family planning and project management that the service provider is urged to utilize in order to fulfill the intent of Title X. The words "can" and "may" indicate options, suggestions, an alternatives for consideration by individual projects.

The "grantee" is the entity that receives a federal grant and assumes legal and financial responsibility and accountability for the awarded funds and for the performance of the activities approved for funding. The "project" consists of those activities described in the grant application and supported under the approved budget. "Delegate agencies" are those entities that provide family planning services with Title X funds under a negotiated, written agreement with a grantee. "Service sites" are those entities actually providing services on-site for the grantee or delegate agency. The word "provide" is used to mean the provision of services on-site and/or by referral, unless otherwise stipulated.

2.0 The Law, Regulations, and Guidelines

To enable persons who desire to obtain family planning care to have access to the requisite services, Congress enacted the Family Planning Services and Population Research Act of 1970 (Public Law 91-572), which added Title X, "Population Research and Voluntary Family Planning Programs," to the Public Health Service Act. Section 1001 of the Act (as amended by Public Laws 94-63 and 95-613) "authorizes grants to assist in the establishment and operation of family planning projects which offer a broad range of acceptable and effective family planning methods, including natural family planning methods, infertility services, and services to adolescents" (see *Attachment A*). The mission of Title X is to provide individuals the information and means to exercise personal choice in determining the number and spacing of their children.

The regulations governing Title X [42 CFR, Subpart A, Part 59], published in the Federal Register on June 3, 1980, are the requirements of the Secretary, Department of Health and Human Services, in the provision of family planning services funded under Title X and implement the statute as authorized under Section 1001 of the Public Health Service Act. Prospective applicants and grantees should refer to the regulations in their entirety (*Attachment B*).

This document, *Program Guidelines for Project Grants for Family Planning Services*, interprets the law and regulations in operational terms and provides a general orientation to the Federal perspective on family planning.

3.0 The Application Process

3.1 ELIGIBILITY

Any public or nonprofit private entity located in a State (which, by definition, includes the District of Columbia, Puerto Rico, Guam, the Virgin Islands, American Samoa, Northern Marianas and the Trust Territory of the Pacific Islands) is eligible to apply for a Title X family planning services project grant [59.2, 59.3]. A nonprofit private agency, institution, or organization must furnish evidence of its nonprofit status in accordance with instructions accompanying the project grant application form. Under the law, grants cannot be made to entities that propose to offer only a single method or a limited number of family planning methods. A facility or entity offering a single

method can receive assistance under Title X by participating as a special service provider in an approvable project that offers a broad range of services [59.5(a)1].

If an application proposes to consolidate service areas or health resources or to otherwise affect the operations of other local or regional entities, the applicant must document that these entities have been given the maximum opportunity to participate in the development of the application. Local and regional entities include existing or potential subgrantees that have previously provided or propose to provide family planning services to the area to be served by the applicant [59.5(a)10(i)].

3.2 NEEDS ASSESSMENT

An assessment of the need for family planning services must be conducted prior to applying for a new grant award. This needs assessment documents the need for family planning services in the service area and should include:

- *Demographic description of the service area;*
- *Description of existing services (e.g., Title V, Community Health Center projects providing family planning services);*
- *Identification of community resources and networks related to reproductive health (e.g., health centers, hospitals);*
- *Identification of high priority services, populations, or target areas (e.g., adolescent services, a low income community).*

Grantees should perform periodic reassessment of service needs. New grant applications should include the initial needs assessment statement. Continuation and renewal grant applications need only provide an update of the previous needs assessment.

3.3 THE APPLICATION

The application form, PHS 5161, with instructions, is available from the appropriate Regional Office of the Department of Health and Human Services (see *Attachment D*). Assistance in the preparation of an application may be sought from the Regional Office.

An application must contain: (1) a narrative description of the project and the manner in which the applicant intends to conduct it in order to carry out the requirements of the law and regulations; (2) a budget that includes an estimate of project income and costs, with justification for the amount of grant funds requested; (3) a description of the standards and qualifications that will be required for all personnel and facilities to be used by the project; and (4) such other pertinent information as may be required [59.4(c)]. The application must address all points contained in section 59.7(a) of the regulations, which are the criteria DHHS will use to decide which family planning projects to fund and in what amount.

An application must also define project objectives that are specific, realistic, and measurable. The application shall not include activities that cannot be funded under Title X, such as abortion, fund raising, or lobbying activities.

3.4 PROJECT REQUIREMENTS

Projects must adhere to:

- Section 59.5 of the regulations, which lists the requirements to be met by each project supported by Title X and which prohibits the provision by the project of abortion services.
- These *Program Guidelines for Project Grants for Family Planning Services*.
- Bureau of Community Health Service (BCHS) requirements applicable to the Title X program (see Appendices).
- Other federal and DHHS regulations which apply to grants made under Title X. These include regulations on sterilization (see *Attachment C*), the Privacy Act [P.L. 93-579], the Freedom of Information Act [45 CFR, 5 and 5b], Human Subjects Clearance, A-95, and those Code of Federal Regulations parts listed in section 59.10 of the regulations. *For assistance in identifying other relevant regulations, contact the Regional Office.*

3.5 NOTICE OF THE GRANT AWARD

The notice of the grant award will inform the grantee how long DHHS intends to support the project without requiring it to recompete for funds [59.8]. This period of funding is called the “project period”. Under the project period system, projects that continue for more than one year may have the program approved for support in its entirety, or for a portion thereof, but the project will be funded in increments called “budget periods”. The budget period is normally twelve months, although shorter or longer budget periods may be established for compelling administrative or programmatic reasons.

4.0 Grant Administration

All projects must comply with grants administration requirements as described in the *DHHS Grants Administration Manual* and the PHS Supplements. The *DHHS Grants Administration Manual* is for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402; the PHS Supplements and the *Public Health Service Grants Policy Statement* may be

obtained from the PHS Regional Offices or the Division of Grants and Contracts, ORM/OAM/PHS, 5600 Fishers Lane, Rockville, MD 20857.

5.0 Legal Issues

5.1 NONDISCRIMINATION

Projects must provide services without regard to religion, race, color, national origin, creed, handicap, sex, number of pregnancies, marital status, age, and contraceptive preference. Services must be provided in a manner that protects the dignity of the individual [59.5(a)3, 4].

5.2 VOLUNTARY PARTICIPATION

Use by any individual of project services must be solely on a voluntary basis. Individuals must not be subjected to coercion to receive services or to use any particular method of family planning. Acceptance of family planning services must not be a prerequisite to eligibility for or receipt of any other service or assistance from or participation in any other programs of the applicant [59.5(a)2].

Project personnel should be informed that they will be subject to legal action if they coerce or endeavor to coerce any person to undergo an abortion or sterilization procedure, as detailed in P.L. 94-63, Section 205 (see *Attachment A*).

5.3 CONFIDENTIALITY

Every project must assure client confidentiality and provide safeguards for individuals against the invasion of personal privacy, as required by the Privacy Act. No information obtained by the project staff about individuals receiving services may be disclosed without the individual*s consent, except as required by law or as necessary to provide services. Information may otherwise be disclosed only in summary, statistical, or other form that does not identify the individual [59.11].

5.4 CONFLICT OF INTEREST

Grantees must establish safeguards to prevent employees, consultants, or members of governing or advisory bodies from using their positions for purposes of private gain for themselves or for others.

5.5 LIABILITY COVERAGE

Programs and projects must ensure the existence of adequate liability coverage for all segments of the program funded under the grant, including personnel providing services. Projects should consider obtaining liability coverage for members of their governing boards.

5.6 HUMAN SUBJECTS CLEARANCE (RESEARCH)

Grantees considering clinical or sociological research must adhere to the legal requirements governing human subjects research, specifically with regard to informed consent. Grantees must advise the Regional Office in writing of research projects involving Title X clients or resources. In order to provide for the adequate discharge of this institutional responsibility, grantees must provide written assurances of (1) compliance with DHHS policy regarding the protection of human subjects, and (2) approval of the research by a properly constituted committee of the grantee institution. The *Office for the Protection from Research, NIH, Bethesda, MD 20014, is responsible for the implementation and enforcement of this policy for DHHS.*

6.0 Program Management

6.1 STRUCTURE OF THE GRANTEE

Family planning services under Title X grant authority may be offered by grantees directly or by delegate agencies operating under the umbrella of the grantee. However, the grantee will be held responsible for the quality, cost, accessibility, acceptability, reporting, and performance of its delegate agencies. Grantees must therefore have a negotiated, written agreement with each delegate agency and establish written standards and guidelines consistent with the appropriate section(s) of the *Program Guidelines for Project Grants for Family Planning Services* for all delegated services. If service sites are funded by delegate agencies or if special service providers are utilized, e.g., providers of fertility awareness methods including natural family planning, a written, negotiated agreement approved by the grantee must be maintained by the delegate. All service providers should be invited to participate in the establishment of grantee standards and guidelines.

6.2 PLANNING AND EVALUATION

All projects receiving Title X funds must provide services of high quality and be competently and efficiently administered. To assist in meeting these requirements, each project must prepare a health care plan which identifies overall goals and specific measurable objectives for the coming year. The objectives may be directed to all clients or to specific groups of clients and should be consistent with Bureau of Community Health Services objectives. The

health care plan must include an evaluation component that addresses and defines indicators by which the project intends to evaluate itself. The health care plans for all delegate agencies and special service providers (e.g., infertility services) must be incorporated into the grantee*s health care plan. These plans should be reviewed regularly by the grantee and be updated periodically to assure project effectiveness. *For further information, see Related Documents—Planning and Evaluation.*

6.3 FINANCIAL MANAGEMENT

Grantees must maintain a financial management system that meets the standards specified in Subpart H of 45 CFR 74, Administration of Grants, and complies with federal standards to safeguard the use of funds. Documentation and records of all income and expenditures must be maintained.

- **!** Charges, Billing, and Collections

  A grantee is responsible for the implementation of policies and procedures for charging, billing, and collecting funds for the services provided by the project. The policies and procedures are approved by the governing board or advisory board and the Regional Office [59.5(a)8]. Billing and collection procedures must have the following characteristics:

  (1) Charges are based on a cost analysis of all services provided by the project. Bills are given directly to the client or to another payment source such as Title XIX, Title XX, or private insurance.

  (2) A schedule of discounts is required for individuals with family incomes between 100% and 250% of poverty based on family size, income, and other specified economic considerations [59.5(a)8]. The upper limit for the schedule of discounts must be based on local circumstances. Substantial justification is expected for a schedule of discounts for which the limit is above 200% of poverty.

  (3) Clients whose documented income is at or below 100% of poverty are not billed, although projects must bill all third parties legally obligated to pay for services [59.5(a)7].

  (4) Individual eligibility for a discount must be documented in the client* record.

  (5) Bills to third parties show total charges without applying any discount [59.5(a)9].

  (6) Where reimbursement is available from Title XIX or Title XX of the Social Security Act, a written agreement is required [59.5(a)9].

  (7) Bills to clients show total charges less any allowable discounts.

  (8) Bills for minors obtaining confidential services shall be based on the resources of the minor.

  (9) Reasonable efforts to collect bills include mailing of bills when client confidentiality is not jeopardized.

  (10) A method for the "aging" of outstanding accounts is to be established.

  (11) Clients must not be denied services because of the inability to pay.

  Effective financial management will assure the short and long term viability of the project, including the efficient use of grant funds. Technical assistance in achieving this objective is available from the Regional Office.

- **!** Financial Audit

  Annual grantee audits must be conducted in accordance with the provision of 45 CFR 74, Subpart H. The audits shall be conducted by auditors meeting established criteria for qualifications and independence. Additional guidance on the performance of audits can be found in the *Guide for Adults of Financial and Business Systems and Federal Assistance Recipients Funded by the Public Health Service*, which is available from the DHHS Office of the Inspection General audit agency.

6.4 FACILITIES AND ACCESSIBILITY OF SERVICES

Family planning facilities and services should be geographically accessible to the population served and should be available at times convenient to those seeking services, i.e., evening and/or weekend hours in addition to daytime hours. The facilities should be adequate to provide the necessary services and should be designed to ensure comfort and privacy for clients and to expedite the work of the staff. Facilities must meet standards established within each State or community (e.g., local fire and building codes) and comply with the *Ambulatory Health Care Standards.* Projects should conform to standards for out-of-hospital facilities when their facilities are used for surgical procedures such as female and male sterilizations.

Projects should be in compliance with 45 CFR, Part 84, regarding discrimination against handicapped persons and requiring that program facilities be made accessible to the handicapped.

6.5 PERSONNEL

Grantees and delegate agencies must establish and maintain written personnel policies that comply with Federal and State requirements and Title VI of the Civil Rights Act. These policies shall include but need not be limited to staff recruitment, selection, performance

evaluation, promotion, termination, compensation, benefits, and grievance procedures.

Grantees shall also ensure:

- *That the medical care component of the project operates under the supervision and responsibility of a medical director who is a licensed and qualified physician with special training or experience in family planning [59.5(b)6];*
- *That when health professionals other than physicians (e.g., nurse practitioners) perform delegated medical functions they do so under protocols and/or standing orders approved by the medical director;*
- *That personnel records be kept confidential;*
- *That an organizational chart and personnel policies be available to all personnel;*
- *That job descriptions be available for all positions, and that these be reviewed annually and updated when necessary to reflect TEXT in duties;*
- *That an evaluation and review of the job performance of all project personnel be conducted annually.*

6.6 TRAINING AND TECHNICAL ASSISTANCE

Projects must provide for the orientation and in-service training of all project personnel, including the staffs of delegate agencies and service sites [59.5(b)4]. Projects should develop an in-service training capability and prepare a training plan for skills development and/or continuing education based on an assessment of training needs. All project personnel should participate in continuing education related to their activities, including on-the-job training, workshops, institutes, and courses. Documentation of attendance should be kept in the project*s records to be used in evaluating the scope and effectiveness of the staff training program.

Training and technical assistance through regional training centers and resources available through other grantees or projects are available to all projects under the Title X program. Information on obtaining these services is available from the Regional Offices. Training and/or travel allowances for training not funded under Title X may be included in the grantee budget with documented justification.

6.7 REPORTING REQUIREMENTS

Projects must comply with the *BCHS Common Reporting Requirements (BCRR)*. In addition, the grantee must file an annual grant report and report of expenditures, and must report user, encounter, revenue, and cost data on the BCRR at intervals specified by the Regional Office. Projects must also comply with other reporting requirements, such as sterilization, State, and local reporting requirements.

6.8 INDICATORS FOR FUNDING

Indicators calculated from the BCRR are among the criteria used to evaluate the productivity and effectiveness of ambulatory health care centers supported by BCHS. These program indicators consist of administrative indicators (e.g., provider productivity, cost per medical encounter) and clinical indicators (e.g., immunization, family planning counseling for adolescents, pap smear follow-up, hypertension screening, and anemia screening). Performance on these indicators, in addition to other project activities and plans described in the grant application, are evaluated for funding purposes. For more details, see the *Instruction Manual for BCHS Common Reporting Requirements and the current Funding Criteria for BCHS Programs*.

6.9 REVIEW AND APPROVAL OF INFORMATIONAL AND EDUCATIONAL MATERIALS

An advisory committee of five to nine members who are broadly representative of the community must review and approve all informational and educational (I and E) materials developed or made available under the project prior to their distribution to assure that the materials are suitable for the population and community for which they are intended and to assure their consistency with the purposes of Title X.

This committee shall (1) consider the educational and cultural backgrounds of the individuals to whom the materials are addressed, (2) consider the standards of the population or community to be served with respect to such materials, (3) review the content of the material to assure that the information is factually correct, (4) determine whether the material is suitable for the population or community to which it is to be made available, and (5) establish a written record of its determinations [59.6].

The committee may delegate responsibility for the review of technical materials (e.g., medical) to appropriate persons or groups, but final responsibility and authority for the approval of I and E materials rests with the committee.

6.10 COMMUNITY PARTICIPATION

Grantees must provide, to the maximum extent feasible, an opportunity for participation in the development, implementation, and evaluation of the project (1) by persons broadly representative of all significant elements of the population to be served, and (2) by persons in the community knowledgeable about the

community*s needs for family planning services [59.5(b)10].

The I and E advisory committee may be utilized to serve the community participation function or a separate group may be identified. In either case, the grantee*s health care plan must include a plan for community participation, and by-laws or guidelines for these activities should be prepared. The community participation committee shall meet at least annually or more often if appropriate.

6.11 PROGRAM PROMOTION

To facilitate community acceptance of and access to family planning services, projects must establish and implement planned activities whereby their services are made known to the community [59.5(b)3]. In planning for program promotion, projects should review a range of strategies and assess the availability of existing resources and materials. The participation of elected, civic, health, and education leaders, youth agency representatives, as well as users of services, should be solicited. Program promotion activities should be updated periodically and be responsive to the changing needs of the community. *For more information, contact the Regional Offices, the Office for Family Planning, and the National Clearinghouse for Family Planning Information, as listed in Attachment D.*

6.12 COMMUNITY EDUCATION

Each family planning project must plan to provide for community education [59.5(b)3]. This should be based on an assessment of the needs of the community and should contain an implementation and evaluation strategy. Community education can be directed toward identifying local agencies and institutions which are likely to serve significant numbers of individuals in need of family planning care, such as schools, postpartum clinics, abortion services, mental health facilities, and clinics for the management of sexually transmitted diseases. Projects should offer orientation sessions for the staffs of these related health and social services in order to help them better counsel and refer potential family planning clients.

Efforts can also be directed toward more general community education about family planning, such as values clarification with regard to family planning, family life, and human sexuality. A variety of approaches should be used, depending on the objectives of the program and the intended audiences. Some examples of techniques are individual contacts by outreach workers, more formal programs or discussions for larger groups or classes, and the use of public service announcements and posters.

Community education can serve to enhance community understanding of the objectives of the program, make known the availability of services to potential clients, and encourage continued participation by persons to whom family planning may be beneficial.

6.13 PUBLICATIONS AND COPYRIGHT

Unless otherwise stipulated, publications resulting from activities conducted under the grant need not be submitted to DHHS for prior approval. It is recommended, however, than an informational copy of any such publication be sent to the National Clearinghouse for Family Planning Information. Projects should assure that publications developed under Title X do not contain information which is contrary to program requirements (45 CFR, 74.145) or to accepted medical practice. Federal grant support must be acknowledged in any publication. Except as otherwise provided in the conditions of the grant award, the author is free to arrange for copyright without DHHS approval of publications, films, or similar materials developed from work supported by DHHS. Restrictions on motion picture film production are outlined in the *Public Health Service Grants Policy Statement*. Any such copyrighted materials shall be subject to a royalty-free, non-exclusive, and irrevocable license or right to the Government to reproduce, translate, publish, use, disseminate, and dispose of such materials and to authorize others to do so.

6.14 INVENTIONS OR DISCOVERIES

Family planning project grant awards are subject to the regulations of DHHS as set forth in 45 CFR, Parts 6 and 8, as amended [59.12]. These regulations shall apply to any activity of the project for which grant funds are used, whether the activity is part of an approved project or is a by-product of the project. The grantee shall take appropriate measures to assure that no contracts, assignments, or other arrangements inconsistent with the grant obligation are entered into or continued and that all personnel involved in the grant activity are aware of and comply with such obligations.

7.0 Client Services

Projects funded under Title X must provide medical, social, and referral services relating to family planning to all eligible clients who desire such services [59.5(b)1,2,8]. Part II of this document has ben developed to provide guidance to grantees as to those services which are *required, recommended, or related* to fulfill the mission and intent of Title X. The *required* services are those services which are stipulated either in the law or the regulations, or which are otherwise considered essential to the provision of family

planning services of high quality. The *recommended* services are those services intended to promote the reproductive and general health care of the family planning client population. The *related* services are those services which are not authorized under Title X but which may be provided by projects in order to meet the specific reproductive-related health needs of the family planning client.

7.1 SERVICE PLANS AND PROTOCOLS

The service plan is the component of the grantee's health care plan which id developed by the medical director and clinical staff and which identifies those services to be provided to clients under Title X by the projects. As part of the service plan, all delegates and/or service sites must have written protocols, approved by the grantee, which detail specific procedures for the provision of each services offered. Plans must be written in accordance with Title X program guidelines and current medical practice and must cover the services provided at initial visits, annual revisits, and other revisits, including supply and problem revisits (see chart 7.1).

Under exceptional circumstances, a waiver form a particular requirement in the guidelines may be obtained from the Regional Office upon written request from an individual project. For example, the hemoglobin or hematocrit requirement may be waived if a project's medical director determines that routine anemia screening is unwarranted in the client populations served. In submitting a request for such an exception, the project must provide epidemiologic, clinical, and other supportive data to justify the request and the duration of the waiver.

7.2 PROCEDURAL OUTLINE

The services provided to family planning clients and the sequence in which they are provided, will depend upon the type of visit and the nature of the services requested. However, the following components should be offered to all clients the initial visit: Presentation of relevant educational materials: initial counseling; explanation of all procedures and signing of an informed consent covering examination and treatment; obtaining of a personal and family history; performance of a physical examination; performance of routine and other laboratory tests; individual counseling; performance of any necessary medical procedures; provision of medications and/or supplies; exit counseling. Return visits should include an assessment of the clients health status and opportunity to change methods.

For clients electing nonprescription methods of contraception or fertility awareness methods including natural family planning, the initial required medical work-up may be deferred at their request, with appropriate documentation in the medical record. Such clients should be encouraged to have health screening at return visits.

7.3 EMERGENCIES

Emergency situation involving clients and/or staff may occur at any time. All projects should therefore have written plans and procedures for the management of on-site medical emergencies (e.g., cardiac arrest, shock, hemorrhage, and respiratory difficulties) with which project staff are familiar. Written plans and procedures should also be available for emergencies requiring ambulance services and/or hospital treatment. Information and instructions on dealing with fire, natural disaster, robbery, power failure, harassment, and other emergency situations should also be available, and appropriate training in these areas should be provided to staff.

7.4 REFERRALS AND FOLLOW-UP

Grantees must provide all family planning services listed under "Required Services" either on-site or by referral. When required series are to be provided by referral, the grantee must establish formal arrangements with a referral agency for the provision of series and reimbursement of costs, as appropriate. Title X funds may be used to cover the cost of these referred services only if other sources of funds are available.

For other than reburied services, that is services which are determined to be necessary but which are beyond the scope of the program, clients should be referred to other providers for care. Examples of such referrals are: treatment for gynecologic dysplasia or malignancy, pregnancy management, family or general medical practices, general surgery, genetic testing, dentistry, mental health services, marriage/sexual counseling , services related to abortion, and other social services. grantees should maintain a list of health care providers, local health and welfare departments, hospitals, voluntary agencies, and health service project supported by other Federal programs [59.6(b)2] to use of referral purposes. Projects must select referral providers according to procedures which assure fairness in the referral practice and which identify providers of acceptable quality. Whenever possible, clients should be given a choice of providers from which to select.

Projects should have written referral and follow-up procedures. The timing and manner of referral and follow-up depend upon the nature of the problem for which the referral was made. For example:

- *Emergency referrals (e.g., possible ectopic pregnancy) should be made immediately with the provider.*

Chart 7.1

Legend X = Routine
(X) = If Indicated

MINIMUM REQUIREMENTS FOR ROUTINE CONTRACEPTIVE MANAGEMENT

	ORAL CONTRACEPTIVES				IUD		DIAPHRAGM			
	FIRST COMPLETE VISIT ALL METHODS	3 mos. after initial Rx	every 6 mos. for high risk	every 12 mos.	within 3 mos. of insertion	every 12 mos.	Preferably within 1 month of fitting	every 12 mos	NON PRESCRIPTIVE METHODS every 12 mos.	EVERY 24 MOS. ALL METHODS
A. HISTORY										
1. General	X			(Update)		(Update)		(Update)	(Update)	UPDATE
2. Method Specific		X	X	X	X	X	X	(X)	(X)	X
B. PHYSICAL EXAM										
1. General	X		(X)	(X)		(X)		(X)	(X)	X
2. Method Specific	X		(X)	X	X	X	check fit	(X)	(X)	X
3. Weight	X	X	X	X		(X)		(X)	(X)	X
4. Blood pressure	X	X	X	X		X		(X)	(X)	X
C. LABORATORY										
1. Hct &/or Hgb	X			(X)	(X)	X		(X)	(X)	(X)
2. Urinalysis	(X)		(X)	(X)		(X)		(X)	(X)	(X)
3. Pap smear	X			X		X		(X)	(X)	(X)
4. GC culture	(X)[1]			(X)		(X)		(X)	(X)	(X)
5. Serology	X									
6. Rubella liter	(X)									
D. EDUCATION	X	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)
E. COUNSELING	X	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)

[1]Gonorrhea cultures must be provided to clients requesting IUD insertion.

Ncte: This schedule provides guidance for the management of asymplornalic contraceptive users only.

- *Urgent referrals (e.g., solitary breast nodule) should be followed up within two weeks with the client.*
- *Essential referrals (e.g., hypertension) should be followed up with the client, the timing to depend on professional judgment.*
- *Discretionary referrals (made at the request of the client) should be followed up with the client at the next clinic visit. Further follow-up may not be necessary but should be based on professional judgment.*

Projects should make arrangement for the transfer (with client consent) of pertinent client information to the referral provider. In addition, internal systems should be developed to document (1) that recommended referral appointments are made within appropriate period of time, (2) that these appointments are kept, (3) that providers return complete pertinent clients information to the referring center, (4) action taken in response to recommendations received from the referral providers, and (5) any comments the client makes about the referral providers. Efforts may be made to aid the client in identifying potential resources for reimbursement of the referral providers, but projects are not responsible for the cost of this care.

When family planning services are provided by the project to clients referred from other agencies, the projects has a responsibility to share client information with the referring agency. Such information may only be given with the written permission of the client.

When family planning clients are referred for services, projects have a responsibility to assure that clients obtain the appropriate services , and referred clients should be contacted to assure that the series are obtained. However, follow-up must be negotiated with the clients on the first visit, and the negotiated method for follow-up should be noted on the follow-up care and the clients medial record.

8.0 Required Services

The services contained in this section *must* be provided by all projects funded under Title X.

8.1 CLIENT EDUCATION

Education services should provide clients with the information they need to make informed decisions about family planning, to use specific methods of contraception, and to understand the procedures involved in the family planning clinic visit. On an initial visit clients should be offered information about basic female and male anatomy and physiology and the value of fertility regulation in maintaining individual and family health. The range of available services and the purpose and sequence of clinic procedures should also be explained. Clients must be given information about all contraceptive methods in order to make informed choice. This instruction should be documents in the client record. Additional education, particularly at subsequent visits, house include information on reproductive health and health promotion/disease prevention, as appropriate.

The project's education component should include written goals, content outlines and procedures, and an evaluation strategy. The educational approach use should be appropriate to the patient's age, situation, and previously acquired information on the various methods. Providers of education should have a mechanics to determine that information given has been understood.

- Informed Consent

  For ethical, medical and legal reasons, an informed consent documenting the clients voluntary consent to receive the projects services must be signed by the client prior to his or her receiving any medical series. The forms should be written in the primary language of the client or witnesses by an interpreter. It should coverall procedures and medications to be provided. To give informed consent for contraception, the client must receive education on the benefits and risks of the various contraceptive alternatives and entails on the safety, effectiveness, potential side effects, complications, and danger signs of the contraceptive method, including sterilization, should be part of the project's service plan.

  All forms should contain a statement that the client has been counseled, has read the appropriate informational materials, and has understood the content of both. The signed informed consent should be part of the client's record. It should be renewed and updated when there is a major change in the client's health status or a change to a different prescriptive contraceptive method.

  When sterilization services are provided or arranged for with Government funding, Federal sterilization consent guidelines must be followed (see *Attachment C*).

8.2 COUNSELING

The primary purpose of counseling in the family planning setting is to assist clients in reaching an informed decision regarding the choice and continued use of family planning methods and services. The counseling process is designed to help clients resolve uncertainty, ambivalence, and anxiety in relation to reproductive health and to enhance their capacity to arrive at a decision that reflects their considered self interest.

The counseling process involves mutual sharing of information. Persons who provide counseling should be knowledgeable, objective, nonjudgmental, sensitive to the rights and differences of clients as individuals, and able to create an environment in which the client feels comfortable discussing personal information. The counselor*s knowledge should be sufficient to provide ample information regarding the risks, benefits, contraindications, and effective use of any method, procedure, treatment, or option being considered by the client. Documentation of counseling must be included in the client's record.

! Method Counseling
Post-examination counseling should be provided to assure that the client knows results of the history, physical examination, and laboratory studies that may have a bearing on the choice of method(s); knows how to use and is comfortable with the contraceptive method selected and prescribed; knows the common side effects and possible complications of the method selected and what to do in case they occur; knows the planned return schedule and has a next appointment at an appropriate interval; knows an emergency 24 hour telephone number and a location where emergency services can be obtained; and receives appropriate referral for additional services as needed.

! Special Counseling
Clients should receive special counseling regarding future planned pregnancies, management of a current pregnancy, sterilization, and other individual problems (e.g., genetic, nutritional, sexual) as indicated.

8.3 HISTORY, PHYSICAL ASSESSMENT, AND LABORATORY TESTING

- History
A comprehensive personal history and pertinent history of immediate family members must be obtained on all female clients. This should be done at the initial medical visit. The history should be updated at subsequent visits. Histories are recommended for all male clients and are required for those requesting medical services. The initial history should address the following areas:
--Allergies; immunizations, especially rubella; current use of prescription and over the counter medications; significant illnesses; hospitalizations; surgery; review of systems; extent of use of tobacco, alcohol, and drugs.

Histories of reproductive function in female patients should include:
--Menstrual history; sexual activity; sexually transmitted diseases; contraceptive use; pregnancies; in utero exposure to DES.

On medical revisits, oral contraceptive users must be asked about symptoms of embolic disease and other major complications and side effects. IUD users must be asked, in particular, about symptoms of pelvic infection.
The male reproductive history should include:
--Sexual activity; sexually transmitted diseases; fertility; in utero exposure to DES

- Physical Assessment
Female clients requesting prescriptive methods of contraception (e.g., oral contraceptives, IUDs, diaphragms) must have a general physical examination at the initial medical visit. The initial examination should include at least the following:
--Height; weight; blood pressure; thyroid; heart; lungs; extremities; breasts, including instruction in self exam; abdomen; pelvic examination, including visualization of the cervix and bimanual exam; rectal exam, as indicated.

For oral contraceptive users, initial and annual physical examinations must include evaluation of weight, blood pressure, extremities, breasts, and pelvic organs. For IUD users, initial and annual physical exam, blood pressure, and pelvic exam are required, and a more complete exam is recommended.

Female clients using nonprescriptive methods or diaphragms should have a general physical examination at least every two years. This exam is particularly important for clients who are not receiving general health care elsewhere.

Male clients requesting temporary methods of contraception are not required to undergo physical examination, but should be offered this service, to include:
--Height; weight; blood pressure; thyroid; heart; lungs; abdomen; examination of the genitals and rectum, including palpation of the prostate and instruction in self-exam of the testes.

- Laboratory Testing
The following laboratory procedures should be done on-site for all female clients at the initial visit and must be done for those receiving prescription methods. They may be waived if written results of these tests done within six months at another facility are available.

-Hemoglobin (Hgb) or hematocrit (Hct)
-Pap smear
-Gonorrhea culture for clients requesting IUD insertion

In addition, pregnancy testing and gonorrhea screening must be available and provided upon request.

Initial laboratory procedures should be repeated annually or as indicated. Oral contraceptive users must have annual pap smears, and IUD users must have annual hemoglobins or hematocrits and pap smears.

Gram stains and cultures for gonorrhea, and other laboratory tests as indicated, should be available for male clients.

Every effort should be made to assure that laboratory tests performed by or for the clinic are of high quality. This means that the grantee should assess the credentials of laboratories with which it contracts. If laboratory testing is performed on-site, written protocols for quality control and proficiency testing are necessary.

- Notification of Abnormal Lab Results
A procedure must be established to allow for client notification and adequate follow-up of significantly abnormal laboratory results. This procedure must respect the client*s request to maintain confidentiality. When initial contact is not successful, a reasonable further effort should be made, consistent with the severity of the abnormality.

- Other Laboratory Services or Procedures
The following procedures and lab tests should be provided by the project when medically indicated:
-Screening for non-gonococcal sexually transmitted diseases, e.g., syphilis
-Microscopic examination of vaginal smears and wet mounts for diagnosis of vaginitis
-Microscopic examination and/or culture and sensitivity of urine
-Selected laboratory tests, e.g., blood sugar or cholesterol test for women who are potentially at high risk for oral contraceptive use
-Hemagglutination test for rubella.

Other procedures and lab tests may be indicated for some clients and may be provided on-site or by referral.

C Revisits
Revisit schedules should be individualized based upon the client*s need for education, counseling, and medical care beyond that provided at the initial visit. Younger clients and clients initiating a new contraceptive method may need special opportunities for reassurance and clarification. On the other hand, projects should avoid antagonizing well-informed clients who are comfortable with the method being used; such clients should not be required to return for unwanted counseling or frequent supply visits.

Clients selecting oral contraceptives IUDs, or diaphragms should be scheduled for a revisit within three months after initiation of the method to reinforce its proper use, to check for possible side effects, and to provide additional information as needed. A new client who chooses to continue a method in use upon entry to the program need not return for this early revisit unless a need for reevaluation is determined on the basis of the findings at the initial visit.

Annual revisits are mandatory for clients using oral contraceptives or intrauterine devices and must include at a minimum the components of the history, physical examination, and laboratory procedures as specified for such clients. Annual history updates, exams, and laboratory tests are recommended for all clients. The frequency with which specific procedures are to be routinely repeated should be determined by the medical director and documented in the health care plan.

8.4 FERTILITY REGULATION

Projects must make available, either directly or through referral, all of the DHHS approved methods of contraception. *For recommendations on the management of each method, see Related Documents-Fertility Regulation.*

- Temporary Contraception
Currently, the temporary methods of contraception include barrier methods female and male), IUDs, fertility awareness methods including natural family planning, and hormonal contraceptives. More than one method of contraception can be used simultaneously by a client and should be offered if the client requests it, e.g., the use of two barrier methods, the use of a barrier method with an IUD, or the combination of a barrier method with techniques of ovulation detection. Current FDA guidelines as to relative and absolute contraindications, e.g., package inserts, should be followed.

C Permanent Contraception
Projects must ascertain that the counseling and consent process assures voluntarism and full knowledge of the permanence, risks, and benefits associated with female and male sterilization procedures. Federal regulations must be met if the sterilization procedure is performed or arranged for by the project (see *Attachment C*). For further

guidance, see also *Appendices — Permanent Contraception.*

C Emergency Contraception

Projects must comply with FDA recommendations for the administration of drugs or devices for postcoital contraception.

The use of diethylstilbestrol (DES) within 72 hours of unprotected sexual intercourse around the time of presumed ovulation has been found to be highly effective in preventing pregnancy. However, this drug has been implicated in the development of reproductive abnormalities and fertility-related risks in the offspring of women who took DES during pregnancy. Although the doses and duration of DES use for postcoital contraception are less than those commonly used when DES was prescribed for pregnancy complications, health risks may be similar. It also is possible that women may take the drug as a postcoital contraceptive when already pregnant from a previous intercourse. In such cases, the potential offspring of such pregnancies would be exposed to the risks previously described. In light of these considerations, the following recommendations are made:

—Postcoital contraception with DES in any women should be restricted to situations where no alternative is judged acceptable by a fully informed patient and her physician.

—Thorough birth control counseling should accompany or follow any prescription of DES for postcoital purposes. A principal objective of such counseling should be to discourage women from considering it as a routine method of contraception.

8.5 INFERTILITY SERVICES

Grantees are required by law to make basic infertility services available to clients desiring such services. In fertility services which may be supported by Federal funds are categorized as follows:

-- Level I Includes initial infertility interview, education, examination, appropriate laboratory testing (hemoglobin or hematocrit, pap smear, and culture for gonorrhea), counseling, and appropriate referral.

-- Level II Includes semen analysis, assessment of ovulatory function through basal body temperature and/or endometrial biopsy, and postcoital testing.

-- Level III More sophisticated an complex than Level I and Level II services.

Grantees must provide Level I infertility services as a minimum. Those with infertility programs supervised by physicians with special training in infertility can offer Level II services. However, when considering the scope of the infertility services to be offered to clients, grantees must be aware that such services are expensive, not necessarily successful, and be high risk from medical and legal point os view. It is therefore important that the proportion of the grantee's beget which is to be used for infertility services be determined very carefully.

The grantee's health care plan must have an infertility services component that identifies those services to be provided by each delegate at individual services sites or by referral. The infertility plan must address how services will be provided, including the criteria for diagnosis of infertility, the scope of services, identification of referral sits, follow-up, fees schedules, and payment mechanisms. When referring for Level II or Level III infertility series, efforts should be made to help the client identify sources of funding for these services.

Since infertility may be due to male factors, female factors, or a combination of the two, both partners need to be involved in the infertility evaluation. Adequate education should be provided so that clients understand human reproduction and sexuality as it relates to their particular problem. The benefits and risks of proposed diagnostic and therapeutic measure to be provided on-site must be clearly explained and informed consent obtained.

For further guidance, See Appendices -- Infertility Services.

8.6 PREGNANCY DIAGNOSIS AND COUNSELING

Grantees must provide pregnancy diagnosis and counseling to all clients in need of this service. Pregnancy testing is one of the most frequent reasons for an initial visit to the family planning facility, particularly by adolescents. It is therefore important to use this occasion as an entry point for providing education and counseling about family planning.

Pregnancy cannot be accurately diagnosed and staged through laboratory testing alone. Pregnancy diagnosis consists of a history, pregnancy test, and physical assessment, including pelvic examination. Projects providing pregnancy testing on-site should have available at least one test of high specificity and one of high sensitivity. If the medical examination cannot be performed in conjunction with laboratory testing, the client must be counseled as to the importance of receiving a physical assessment as soon as possible, preferably within 15 days. This can be done on-site, by a provider selected by the client, or by a provider to which the client has been referred by the project. For those clients with positive pregnancy test results who elect to continue the pregnancy, the examination may be deferred, but should be performed within 30 days. For clients with a negative pregnancy diagnosis, the cause of delayed menses should be

investigated. If ectopic pregnancy is suspected, the client must be referred for immediate diagnosis and therapy.

Pregnant women should be offered information and counseling regarding their pregnancies. Those requesting information on options for the management of an unintended pregnancy are to be given non-directive counseling on the following alternative courses of action, and referral upon request:

• *Prenatal care and delivery*

• *Infant care, foster care, or adoption*

• *Pregnancy termination*

Clients planning to carry their pregnancies to term should be given information about good health practices during early pregnancy, especially those which serve to protect the fetus during the first three months (e.g., good nutrition, avoidance of smoking, drugs, and exposure to x-rays) and referral for prenatal care.

Clients who are found not to be pregnant should be given information about the availability of contraceptive and infertility services.

For further information, contact the National Clearinghouse for Family Planning Information, as listed in Attachment D.

8.7 ADOLESCENT SERVICES

Adolescent clients require skilled counseling and detailed information. Appointments should be available to them for counseling and medical services on short notice.

It is important not to assume that adolescents are sexually active simply because they have come for family planning services. Many teenagers are seeking assistance in reaching this decision. Abstinence is a valid and responsible option and should be discussed. Adolescents must be assured that the sessions are confidential and that any necessary follow up will assure the privacy of the individual. However, counselors should encourage young clients to discuss their needs with parents or other family members.

Adolescents seeking contraceptive services should be informed about all methods of contraception. As their needs frequently change, counseling should prepare them to use a variety of methods effectively. In addition, teenagers and their partners should be encouraged to participate fully in project medical services, including physical examination and laboratory studies. However, as some teenagers may fear the medical procedures usually performed at the first clinic visit, projects may defer them for those teenagers who request deferral and elect nonprescription methods.

Because there is a high incidence of sexually transmitted diseases (STD) among teenagers, it is appropriate to ask them about symptoms or possible exposure to these infections. Teens at particularly high risk of STD should be urged to undergo examination and treatment as indicated, either directly or by referral.

For further recommendations, see Appendices-Adolescent Services.

8.8 SEXUALLY TRANSMITTED DISEASES (STD)

Projects must provide an initial gonorrhea culture for women requesting IUD insertion. Gonorrhea cultures should also be provided for clients with probable or definite exposure to gonorrhea and hose with symptoms and signs suggesting gonococcal infection. Projects must comply with State and local STD reporting requirements

Treatment of a clients and partner(s) for gonorrhea should be provided through the project. When treatment is provided on-site, appropriate follow-up measures must be undertaken to ensure cure of all persons treated. If parenteral antibiotics are administered, personnel capable of handling an anaphylactic reaction must be in attendance, and appropriate resuscitation drugs and equipment must be available.

For further information, see Appendices -- Sexually Transmitted Disease.

8.9 IDENTIFICATION OF ESTROGEN-EXPOSED OFFSPRING

The daughters and sons of women who received DES or similar hormones during pregnancy may ha ve abnormalities of their reproductive systems or other fertility-related risks. As part of the history, clients born between 1940 and 1970 should be asked to find out whether or not their mothers took estrogens during pregnancy. Clients prenatally exposed to estrogens should receive special screening either on-site or by referral. Female clients should be made aware that they are at risk for developing a rare cervico-vaginal tumor and for a number of complications of pregnancy. Male clients should be made aware that they are at risk of certain lesions of the genital tract and for decreased fertility.

For further recommendations, see Appendices -- Estrogen-Exposed Offspring.

9.0 Recommended Services

Since the services contained in this section are important to reproductive health care, it is recommended that they be provided at individual service sites.

9.1 GONORRHEA SCREENING

In community or client populations with a high incidence of gonorrhea, endocervical cultures for gonorrhea should be performed on each female client at the time of the initial pelvic examination and repeated as indicated. A yield of equal to or greater than 4 percent positive cultures merits universal screening .

For additional guidance, see Appendices—Sexually Transmitted Diseases.

9.2 GYNECOLOGIC PROBLEMS

Family planning programs should provide for the diagnosis and treatment of minor gynecologic problems so as to avoid fragmentation or lack of medical care for clients with these conditions. Problems such as vaginitis or urinary tract infection may be amenable to on-the-spot diagnosis and treatment, following microscopic examination of vaginal secretions or urine.

9.3 GENETIC INFORMATION AND REFERRAL

For clients at risk for transmission of genetic abnormalities, some basic effort to define this risk is a logical component of family planning services. Initial genetic screening and referral services should be offered to clients who are in need of such services.

Initial screening consists of a careful family history of the client and the client's partner. More complete genetic screening and counseling may be offered *directly* (by a genetic counselor who functions in association with a clinical genetics team capable of providing comprehensive services for a broad range of genetic disorders) or *indirectly* (through referral to a comprehensive genetic service program or programs which may be federally, State, or privately funded). In either case, linkages with a comprehensive genetic service program should be established, specifically with clinical genetic services centers.

Where feasible, in-service training in genetics should be arranged for project staff to enable them to provide simple genetic screening. Training may be appropriately provided by a genetic service program to which the project is linked. The purpose of training is to familiarize staff with the indications for genetic services, referral mechanisms, and resources. Literature and informational material regarding the availability of genetic services, including but not limited to prenatal diagnosis, should be available in the appropriate language to all clients on request.

When genetic screening services are offered by a project, they must (1) be supported by a program of public information and education which is sensitive to the concerns of local ethnic and religious groups and upholds the dignity of individuals with congenital physical or mental limitations, (2) include education and counseling to all clients on a voluntary basis, and (3) include referral for testing or further screening if indicated.

For additional guidance, see Appendices—Genetic Screening.

9.4 HEALTH PROMOTION/DISEASE PREVENTION

For many clients, family planning programs are their only continuing source of health information and medical care. Therefore, while most of the client services will necessarily relate to fertility regulation, family planning programs should, whenever possible, provide health maintenance services such as screening, immunization, an general health education and counseling directed toward health promotion and disease prevention. These additional services should promote the client's general state of health and, in turn, the health of their infants and children. Programs are therefore encouraged to assess the health problems prevalent among the populations they serve and to develop services to address them.

Nutrition services are an example of an important activity directed toward promoting health and preventing disease which can be integrated into the existing family planning services. Projects should provide nutritional problem identification, basic nutrition information, screening, and medical care to clients at high risk of nutrition problems or those requiring nutritional management of disease. These services can be provided without the resources of a fulltime nutritionist. Project staff can deliver such services with nutrition training and consultation with a qualified nutritionist.

For further information, see Appendices - Health Promotion/Disease Prevention.

10.0 Related Services

There are some reproduction related health services that projects may offer if skilled personnel and equipment are available, since to send clients elsewhere for diagnosis and treatment could contribute to fragmentation of medical care or result in no care. If such services are to be offered, however, projects should seek funds from appropriate agencies (e.g., a Title V agency for prenatal care) or arrange to cover the cost for care through third party payments (including government agencies) or patient fees.

If a project plans to provide any related services, the following conditions must be met

- *The project must assure that skilled personnel, equipment, and medical backup services are available, and*

- *The project must receive approval from the Regional Office.*

10.1 PRENATAL CARE

Clients with confirmed pregnancies who wish to continue them to term must receive counseling and continuing care. Projects must therefore refer pregnant clients for adequate prenatal care. However, projects may provide prenatal care if the following conditions are met:

- *Documentation shows an unmet need and lack of other adequate sources of prenatal care;*
- *The project has the capability to provide prenatal care for non-high risk clients in accordance with standards developed by The American College of Obstetricians and Gynecologists;*
- *Sources for newborn care are identified prior to delivery;*
- *The institutions to which clients will be referred for delivery and management of complications have been involved in the establishment of the prenatal care service and assure continuity of care;*
- *The project has appropriate linkages for referral of high risk clients or those who become high risk during the course of pregnancy;*
- *Specific prior approval has been obtained from the Regional Office.*

Projects offering prenatal care must utilize all other sources of funding for such services before applying Title X funds for this activity.

For further information, see Appendices and Related Documents—Maternity Services.

10.2 POSTPARTUM CARE

Family planning programs may provide postpartum care for uncomplicated cases in collaboration with local agencies or institutions which provide prenatal and/or intrapartum care. If a family planning program undertakes responsibility for postpartum care, such care should be directed toward assessment of the woman*s physical health, initiation of contraception if desired, and counseling and education related to parenting, breast feeding, infant care, and family adjustment.

For further information, see Appendices and Related Documents—Maternity Services.

10.3 SPECIAL GYNECOLOGIC PROCEDURES

Procedures such as colposcopy, biopsy, and cryosurgery are useful in the diagnosis and management of gynecologic abnormalities. Since such procedures and management require specialized training, they may be provided only under the supervision of a specially qualified physician who has had appropriate training and experience in the colposcopic diagnosis and management of cervical disease. Provision of this service must be limited to the treatment of benign cervical disease. Care must be taken to assure that provision of these procedures does not direct either professional or financial resources from the provision of basic family planning services.

11.0 Clinic Management

11.1 EQUIPMENT AND SUPPLIES

Equipment and supplies shall be safe, adequate, and appropriate to the type of care offered by the project.

It is the responsibility of the medical director to assure proper selection and maintenance of equipment and supplies.

11.2 PHARMACEUTICALS

Projects must be operated in accordance with State and Federal laws relating to security and record keeping for drugs and devices. The prescription of pharmaceuticals must be done under the direction of a physician. However, inventory, supply, and provision of pharmaceuticals may be delegated by the medical director to appropriately qualified health professionals in accordance with State laws regarding such delegation.

It is essential that each facility maintain an adequate supply and variety of drugs and devices to meet the contraceptive needs of is clients. If special services are offered that require the dispensing of additional medications, these should also be part of the inventory. Each facility must maintain emergency resuscitative drugs, supplies, and equipment appropriate to the complexity of the program. These should be in a location readily accessible to the examination and treatment rooms. Facilities providing medical services shall, as a minimum, have readily available those elements needed for the treatment of vasovagal shock.

Contraceptive and therapeutic pharmaceuticals must be kept in a secure place, either under direct and continuous observation or locked. Clinics which stock narcotics and tranquilizing drugs must keep records proving count of the medications at the beginning and end of each day during which drugs are used. State laws with regard to accountability must be followed. If Federal or State statutes pertaining to record keeping, inventory, and dispensing cannot be met by the program, or if community standards of good medical care in the performance of the above activities cannot be met, projects should contract for such services.

11.3 MEDICAL RECORDS

Projects must establish a medical record for every

client who obtains medical services. These records must be maintained in accordance with accepted medical standards. Records must be:

--Complete and accurate, including documentation of telephone encounters of a medical nature;

--Signed by the physician or other appropriately trained health professional making the entry, including name and title;

--Readily accessible;

--Systematically organized to facilitate retrieval and compilation of information;

--Confidential;

--Safeguarded against loss or use by unauthorized persons;

--Secured by lock when not in use;

--Available upon request to client.

- Content of the Client Record.

The client's medical record must contain sufficient information to identify the client, indicate where and how the client can be contacted, justify the clinical impression or diagnosis, and warrant the treatment and end results. The required content of the medical record includes:

— Personal data
— Medical history, physical exam, laboratory test orders, results, and followup
— Treatment and special instructions
— Scheduled revisits

The record must also contain reports of clinical findings, diagnostic and therapeutic orders, and documentation of continuing care, referral, and followup. The record must allow for entries by the counseling and social service staff. Projects should maintain a problem list at the front of each chart listing identified problems to facilitate continuing evaluation and follow-up.

- Confidentiality and Release of Records

A confidentiality assurance statement must appear on the client*s record. The written consent of the client is required for the release of personally identifiable information, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality [59.11]. When information is requested, projects should release only the specific information requested. Information collected for reporting purposes may be disclosed only in summary, statistical, or other form which does not identify particular individuals. Clients transferring to other providers should be provided with a copy of their record to expedite continuity of care.

For more information, see Appendices- Medical Records.

11.4 QUALITY ASSURANCE AND AUDIT

Projects must develop a quality assurance system that provides for the continued development and evaluation of their services. The quality assurance system should include:

• A health care plan based on community needs assessment which specifies all services to be provided routinely by the project and which may also include additional services for specific population groups;

•A tracking system to identify clients in need of follow-up and/or continuing care;

•Quality review procedures to evaluate project performance, to provide feedback to providers and clients, and to initiate corrective action when deficiencies are noted.

Medical audits to determine conformity with standards must be an ongoing activity. Monthly review of a reasonable number of client records is an essential part of quality assurance.

For further information, see Appendices— Quality Assurance/Audit **.**

Attachment A

TITLE X - POPULATION RESEARCH AND VOLUNTARY FAMILY PLANNING PROGRAMS

PROJECT GRANTS AND CONTRACTS FOR FAMILY PLANNING SERVICES

SEC. 1001 [300]

(a)The Secretary is authorized to make grants to and enter into contracts with public or nonprofit private entities to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents). To the extent practicable, entities which receive grants or contracts under this subsection shall encourage family participation in projects assisted under this subsection.

(b)In making grants and contracts under this section the Secretary shall take into account the number of patients to be served, the extent to which family planning services are needed locally, the relative need of the applicant, and its capacity to make rapid and effective use of such assistance. Local and regional entities shall be assured the right to apply for direct grants and contracts under this section, and the Secretary shall by regulation fully provide for and protect such right.

(c)The Secretary, at the request of a recipient of a grant under subsection (a), may reduce the amount of such grant by the fair market value of any supplies or equipment furnished the grant recipient by the Secretary. The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment on which the reduction of such grant is based. Such amount shall be deemed as part of the grant and shall be deemed to have been paid to the grant recipient.

(d)For the purpose of making grants and contracts under this section, there are authorized to be appropriated $30,000,000 for the fiscal year ending June 30, 1971; $60,000,000 for the fiscal year ending June 30, 1972; $111,500,000 for the fiscal year ending June 30, 1973, $111,500,000 each for the fiscal years ending June 30, 1974, and June 30, 1975; $115,000,000 for fiscal year 1976;
$115,000,000 for the fiscal year ending September 30, 1977;
$136,400,000 for the fiscal year ending September 30, 1978;
$200,000,000 for the fiscal year ending September 30, 1979;
$230,000,000 for the fiscal year ending September 30, 1980;
$264,500,000 for the fiscal year ending September 30, 1981;
$126,510,000 for the fiscal year ending September 30, 1982;
$139,200,000 for the fiscal year ending September 30, 1983;
$150,030,000 for the fiscal year ending September 30, 1984; and
$158,400,000 for the fiscal year ending September 30, 1985.

FORMULA GRANTS TO STATES FOR FAMILY PLANNING SERVICES

SEC. 1002 [300a]

(a)The Secretary is authorized to make grants, from allotments made under subsection (b), to State health authorities to assist in planning, establishing, maintaining, coordinating, and evaluating family planning services. No grant may be made to a State health authority under this section unless such authority has submitted, and had approved by the Secretary, a State plan for a coordinated and comprehensive program of family planning services.

(b)The sums appropriated to carry out the provisions of this section shall be allotted to the States by the Secretary on the basis of the population and the financial need of the respective States.

(c)For the purposes of this section, the term "State" includes the Commonwealth of Puerto Rico, the Northern Mariana Islands, Guam, American Samoa, the Virgin Islands, the District of Columbia, and the Trust Territory of the Pacific Islands.

(d)For the purpose of making grants under this section, there are authorized to be appropriated $10,000,000 for the fiscal year ending June 30, 1971; $15,000,000 for the fiscal year ending June 30, 1972; and $20,000,000 for the fiscal year ending June 30, 1973.

TRAINING GRANTS AND CONTRACTS; AUTHORIZATION OF APPROPRIATIONS

SEC. 1003 [300a-1]

(a) The Secretary is authorized to make grants to public or nonprofit private entities and to enter into contracts with public or private entities and individuals to provide the training for personnel to carry out family planning service programs described in section 1001 or 1002 of this title.

(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated $2,000,000 for the fiscal year ending June 30, 1971; $3,000,000 for the fiscal year ending June 30, 1972; $4,000,000 for the fiscal year ending June 30, 1973; $3,000,000 each for the fiscal years ending June 30, 1974 and June 30, 1975; $4,000,000 for fiscal year ending 1976; $5,000,000 for the fiscal year ending September 30, 1977; $3,000,000 for the fiscal year ending September 30, 1978; $3,100,000 for the fiscal year ending September 30, 1979; $3,600,000 for the fiscal year ending September 30, 1980; $4,100,000 for the fiscal year ending September 30, 1981; $2,920,000 for the fiscal year ending September 30, 1982; $3,200,000 for the fiscal year ending September 30, 1983; $3,500,000 for the fiscal year ending September 30, 1984; and $3,500,000 for the fiscal year ending September 30, 1985.

RESEARCH

SEC. 1004 [300a-2]

The Secretary may -

(1) conduct, and

(2) make grants to public or nonprofit private entities and enter into contracts with public or private entities and individuals for projects for, research in the biomedical, contraceptive development, behavioral, and program implementation fields related to family planning and population.

INFORMATIONAL AND EDUCATIONAL MATERIALS

SEC. 1005 [300a-3]

(a) The Secretary is authorized to make grants to public or nonprofit private entities and to enter into contracts with public or private entities and individuals to assist in developing and making available family planning and population growth information (including educational materials) to all persons desiring such information (or materials).

(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated $750,000 for the fiscal year ending June 30, 1971; $1,000,000 for the fiscal year ending June 30, 1972; $1,250,000 for the fiscal year ending June 30, 1973; $909,000 each for the fiscal years ending June 30, 1974, and June 30, 1975; $2,000,000 for fiscal year 1976; $2,500,000 for the fiscal year ending September 30, 1977; $600,000 for the fiscal year ending September 30, 1978; $700,000 for the fiscal year ending September 30, 1979; $805,000 for the fiscal year ending September 30, 1980; $926,000 for the fiscal year ending September 30, 1981; $570,000 for the fiscal year ending September 30, 1982; $600,000 for the fiscal year ending September 30, 1983; $670,000 for the fiscal year ending September 30, 1984; and $700,000 for the fiscal year ending September 30, 1985.

REGULATIONS AND PAYMENTS

SEC. 1006 [300a-4]

(a)Grants and contracts made under this subchapter shall be made in accordance with such regulations as the Secretary may promulgate. The amount of any grant under any section of this title shall be determined by the Secretary; except that no grant under any such section for any program or project for a fiscal year beginning after June 30, 1975, may be made for less than 90 per centum of its costs (as determined under regulations of the Secretary) unless the grant is to be made for a program or project for which a grant was made (under the same section) for the fiscal year ending June 30, 1975, for less than 90 per centum of its costs (as so determined), in which case a grant under such section for that program or project for a fiscal year beginning after that date may be made for a percentage which shall not be less

than the percentage of its costs for which the fiscal year 1975 grant was made.

(b)Grants under this title shall be payable in such installments and subject to such conditions as the Secretary may determine to be appropriate to assure that such grants will be effectively utilized for the purposes for which made.

(c)A grant may be made or contract entered into under section 1001 or 1002 for a family planning service project or program only upon assurances satisfactory to the Secretary that--

(1) priority will be given in such project or program to the furnishing of such services to persons from low-income families; and

(2) no charge will be made in such project or program for services provided to any person from a low-income family except to the extent that payment will be made by a third party (including a government agency) which is authorized or is under legal obligation to pay such charge.

For purposes of this subsection, the term "low-income family" shall be defined by the Secretary in accordance with such criteria as he may prescribe so as to insure that economic status shall not be a deterrent to participation in the programs assisted under this title.

(d)(1) A grant may be made or a contract entered into under section 1001 or 1005 only upon assurances satisfactory to the Secretary that informational or educational materials developed or made available under the grant or contract will be suitable for the purposes of this title and for the population or community to which they are to be made available, taking into account the educational and cultural background of the individuals to whom such materials are addressed and the standards of such population or community with respect to such materials.

(2) In the case of any grant or contract under section 1001, such assurances shall provide for the review and approval of the suitability of such materials, prior to their distribution, by an advisory committee established by the grantee or contractor in accordance with the Secretary's regulations. Such a committee shall include individuals broadly representative of the population or community to which the materials are to be made available.

VOLUNTARY PARTICIPATION

SEC. 1007 [300a-5]

The acceptance by any individual of family planning services or family planning or population growth information (including educational materials) provided through financial assistance under this title (whether by grant or contract) shall be voluntary and shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, any other program of the entity or individual that provided such service or information.

PROHIBITION OF ABORTION

SEC. 1008 [300a-6]

None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning.

PLANS AND REPORTS*

SEC 1009

(a)Not later than seven months after the close of each fiscal year, the Secretary shall make a report to the Congress setting forth a plan to be carried out over the next five fiscal years for -

(1) extension of family planning services to all persons desiring such services,

(2) family planning and population research programs,

(3) training of necessary manpower for the programs authorized by this title and other Federal laws for which the Secretary has responsibility and which pertain to family planning, and

(4) carrying out the other purposes set forth in this title and the Family Planning Services and Population Research Act of 1970.

(b)Such a plan shall, at a minimum, indicate on a phased basis--

(1) the number of individuals to be served by family planning programs under this title and other Federal laws

for which the Secretary has responsibility, the types of family planning and population growth information and educational materials to be developed under such laws and how they will be made available, the research goals to be reached under such laws, and the manpower to be trained under such laws;

(2) an estimate of the costs and personnel requirements needed to meet the purposes of this title and other Federal laws for which the Secretary has responsibility and which pertain to family planning programs; and

(3) the steps to be taken to maintain a systematic reporting system capable of yielding comprehensive data on which service figures and program evaluations for the Department of Health and Human Services shall be based.

(c)Each report submitted under subsection (a) shall--

(1) compare results achieved during the preceding fiscal year with the objectives established for such year under the plan contained in the previous such report;

(2) indicate steps being taken to achieve the objectives during the fiscal years covered by the plan contained in such report and any revisions to plans in previous reports necessary to meet these objectives; and

(3) make recommendations with respect to any additional legislative or administrative action necessary or desirable in carrying out the plan contained in such report.

*Note: Section 1009 of the Title X statute was repealed on November 10, 1998 by Public law 105-362 the Federal Reports Elimination Act of 1998.

PART 59--GRANTS FOR FAMILY PLANNING SERVICES

Subpart A--Project Grants for Family Planning Services

Sec.

Authority: The provisions of this Subpart A are issued under sec. 6(c), 84 Stat. 1507, 42 U.S.C. 300a-4; sec 6(c), 84 Stat. 1506 42 U.S.C. 300.

Source: Federal Register/Vol. 45 No. 108/Tuesday, June 3, 1980/Rules and Regulations

§ 59.1 To what programs do these regulations apply?

The regulations of this subpart are applicable to the award of grants under section 1001 of the Public Health Service Act (42 U.S.C. 300) to assist in the establishment and operation of voluntary family planning projects. These projects shall consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children.

§59.2 Definitions.

As used in this subpart:

"Act" means the Public Health Service Act, as amended.

"Family" means a social unit composed of one person, or two or more. persons living together, as a household.

"Low income family" means a family whose- total annual income does not exceed 100 percent of the most recent Community Services Administration Income Poverty Guidelines (45 CFR 1060.2). "Low-income family" also includes members of families whose annual family income exceeds this amount, but who, as determined by the project director, are unable, for good reasons, to pay for family planning services. For example, unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources.

"Nonprofit," as applied to any private agency, institution, or organization, means that no part of the entity's net earnings benefit, or may lawfully benefit, any private shareholder or individual.

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

"State" means one of the 50 States, the District of Columbia, Puerto Rico, Guam, the Virgin. Islands, American Samoa, Northern Marianas, or the Trust Territory of the Pacific Islands.

§ 59.3 Who is eligible to apply for a family planning services grant?

Any public or nonprofit private entity in a State may apply for a grant under this subpart.

§ 59.4 How does one apply for a family planning services grant?

(a) Application for a grant under this subpart shall be made on an authorized form.

(b) An individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of the grant, including the regulations of this subpart, must sign the application.

(c) The application shall contain-

(1) a description, satisfactory to the Secretary, of the project and how it will meet the requirements of this subpart;

(2) a budget and justification of the amount of grant funds requested;

(3) a description of the standards and qualifications which will be required for all personnel and for all facilities to be used by the project; and

(4) such other pertinent information as the Secretary may require.

§ 59.5 What requirements must be met by a family planning project?

(a) Each project supported under this subpart must:

(1) Provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including infertility services and services for adolescents). If an organization offers only a single method of family planning, such as natural family planning, it may participate as part of a project as long as the entire project offers a broad range of family planning services.

(2) Provide services without subjecting individuals to any coercion to accept services or to employ or not to employ any particular methods of family planning. Acceptance of services must be solely on a voluntary basis and may not be made a prerequisite to eligibility for, or receipt of, any other service, assistance from or participation in any other program of the applicant.[2]

(3) Provide services in a manner which protects the dignity of the individual.

(4) Provide services without regard to religion, race. color, national origin. handicapping condition, age. sex, number of pregnancies, or marital status.

(5) Not provide abortions as a method of family planning.

(6) Provide that priority in the provision of services will be given to persons from low income families.

(7) Provide that no-charge will be made for services provided to any person from a low-income family except to the extent that payment will be made by a third party (including a Government agency) which is authorized to or is under legal obligation to pay this charge.

(8) Provide that charges will be made for services to persons other than those from low-income families in accordance with a schedule of discounts based on ability to pay, except that charges to persons from families whose annual income exceeds 250

percent of the levels set forth in the most recent CSA Income Poverty Guidelines (45 CFR 1060.2) will be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services.

---

[2] Section 205 of Pub. L 94-63 states: "Any (l) officer or employee of the United States (2) officer or employee of any State, political subdivision of a State, or any other entity, which administers or supervises the administration of any program receiving Federal financial assistance or (3) person who receives, under any program receiving Federal assistance, compensation for service, who coerces or endeavors to coerce any person to undergo an abortion or sterilization procedure, by threatening such person with the loss of, or disqualification for the receipt of any benefit or service under a program receiving Federal financial assistance shall be fined not more than $1,000 or imprisoned for not more than one year, or both."

(9) If a third party (including a Government agency) is authorized or legally obligated to pay for services, all reasonable efforts must be made to obtain the third-party payment without application of any discounts. Where the cost of services is to be reimbursed under title XIX or title XX of the Social Security Act, a written agreement with the title XIX or title XX agency is required.

(10)(i) Provide that if an application relates to consolidation of service areas or health resources or would otherwise affect the operations of local or regional entities, the applicant must document that these entities have been given, to the maximum feasible extent, an opportunity to participate in the development of the application. Local and regional entities include existing or potential subgrantees which have previously provided or propose to provide family planning services to the area proposed to be served by the applicant.

(ii) Provide an opportunity for maximum participation by existing or potential subgrantees in the ongoing policy decision making of the project.

(11) Provide for an Advisory Committee as required by §59.6.

(b) In addition to the requirements of subsection (a) of this section, each project must meet each of the following requirements unless the Secretary determines that the project has established good cause for its omission. Each project must:

(1)Provide for medical services related to family planning (including physician's consultation, examination prescription, and continuing supervision, laboratory examination, contraceptive supplies) and necessary referral to other medical facilities when medically indicated, and provide for the effective usage of contraceptive devices and practices.

(2) Provide for social services related to family planning, including counseling, referral to and from other social and medical service agencies, and any ancillary services which may be necessary to facilitate clinic attendance.

(3) Provide for informational and educational programs designed to (i) achieve community understanding of the objectives of the program, (ii)inform the community of the availability of services, and (iii) promote continued participation in the project by persons to whom family planning services may be beneficial.

(4) Provide for orientation and inservice training for all project personnel.

(5) Provide services without the imposition of any durational residency requirement or requirement that the patient be referred by a physician.

(6) Provide that family planning medical services will be performed under the direction of a physician with special training or experience in family planning.

(7) Provide that all services purchased for project participants will be authorized by the protect director or his designee on the project staff.

(8) Provide for coordination and use of referral arrangements with other providers of health care services, local health and welfare departments, hospitals, voluntary agencies. and health services projects supported by other Federal programs.

(9) Provide that if family planning services are provided by contact or other similar arrangements with actual providers of services, services will be provided in accordance with a plan which establishes rates and methods of payment for medical care. These payments must be made under agreements with a schedule of rates and payment procedures maintained by the grantee. The grantee must be prepared to substantiate that these rates are reasonable and necessary.

(10) Provide, to the maximum feasible extent, an opportunity for participation in the development, implementation and evaluation of the project by persons broadly representative of all significant elements of the population to be served, and by others in the community knowledgeable about the community's needs for family planning services.

§ 59.6 What procedures apply to assure the suitability of informational and educational material?

(a) A grant under this section may be made only upon assurances satisfactory to the Secretary that the project shall provide for the review and approval of informational and educational materials developed or made available under the project by an Advisory Committee prior to their distribution, to assure that the materials are suitable for the population or community to which they are to be made available and the purposes of title X of the Act. The project shall not disseminate any such materials which are not approved by the Advisory Committee.

(b) The Advisory Committee referred to in subsection (a) of this section shall be established as follows:

(1) Size. The Committee shall consist of no fewer than five but not more than nine members, except that this provision may be waived by the Secretary for good cause shown,

(2) Composition. The Committee shall include individuals broadly representative (in terms of demographic factors such as race, color, national origin, handicapped condition, sex, and age) of population or community for which the materials are intended.

(3) Function. In reviewing materials, the Advisory Committee shall:

(i)Consider the educational and cultural backgrounds of individuals to whom the materials are addressed;

(ii) Consider the standards of the population or community to be served with respect to such materials;

(iii) Review the content of the material to assure that the information is factually correct;

(iv) Determine whether the material is suitable for the population or community to which it is to be made available; and

(v) Establish a written record of its determinations.

§ 59.7 What criteria will Health and Human Services use to decide which family planning services projects to fund and in what amount?

(a) Within the limits of funds available for these purposes, the Secretary may award grants for the establishment and operation of those projects which will in the Department's judgment best promote the purposes of section 1001 of the Act, taking into account:

(1) The number of patients and, in particular, the number of low-income patients to be served;

(2) The extent to which family planning services are needed locally;

(3) The relative need of the applicant;

(4) The capacity of the applicant to make rapid and effective use of the Federal assistance;

(5) The adequacy of the applicant's facilities and staff;

(6) The relative availability of non-Federal resources within the community to be served and the degree to which those resources are committed to the project; and

(7) The degree to which the project plan adequately provides for the requirements set forth in these regulations.

(b) The Secretary shall determine the amount of any award on the basis of his estimate of the sum necessary for the performance of the project. No grant may be made for less than 90 percent of the project's costs, as so estimated, unless the grant is to be made for a project which was supported, under section 1001, for less than 90 percent of its costs in fiscal year 1975. In that case, the grant shall not be for less than the percentage of costs covered by the grant in fiscal year 1975.

(c) No grant may be made for an amount equal to 100 percent of the project's estimated costs.

§ 59.8 How is a grant awarded?

(a) The notice of grant award specifies how long HHS intends to support the project without requiring the project to recompete for funds. This period, called the project period, will usually be for 3 to 5 years.

(b) Generally the grant will initially be for 1 year and subsequent continuation awards will also be for 1 year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the Government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

§ 59.9 For what purpose may grant funds be used?

Any funds granted under this subpart shall be expended solely for the purpose for which the funds were granted in accordance with the approved application and budget, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed in Subpart Q of 45 CFR Part 74.

§ 59.10 What other HHS regulations apply to grants under this subpart?

Attention is drawn to the following HHS Department-wide regulations which apply to grants under this subpart. These include;

42 CFR Part 50--PHS Informal Grant Appeals Procedure

45 CFR Part 16--Department Grant Appeals Process

45 CFR Part 19--Limitation on Payments or Reimbursements for Drugs

45 CFR Part 74-Administration of Grants

45 CFR Part 80--Nondiscrimination Under Programs Receiving Federal Assistance Through the Department of Health and Human Services' Implementation of Title VI of the Civil Rights Act of 1964

45 CFR Part 81--Practice and Procedures for Hearings Under Part 80

45 CFR Part 84--Nondiscrimination on the basis of Handicap in Programs and Activities Receiving or Benefiting from Federal Financial Assistance

45 CFR Part 90--Nondiscrimination on the Basis of Age in Programs or Activities Receiving Federal Financial Assistance.

42 CFR Part 122, Subpart E -- Health System Agency Reviews of Certain Proposed Uses of Federal Health Funds.

§ 59.11 Confidentiality.

All information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and must not be disclosed without the individual's consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. Otherwise, infomation may be disclosed only in summary, statistical, or other form which does not identify particular individuals.

§ 59.12 Inventions or discoveries

(a) A project grant award is subject to the regulations of HHS as set forth in 45 CFR Parts 6 and 8, as amended. These regulations shall apply to any activity of the project for which grant funds are used, whether the activity is part of an approved project or is an unexpected byproduct of that project

(b) The grantee and the Secretary shall take appropriate measures to assure that no contracts, assignments, or other arrangements inconsistent with the grant obligation are continued or entered into and that all personnel involved in the grant activity are aware of and comply with such obligations.

§ 59.13 Additional conditions.

The Secretary may, with respect to any grant, impose additional conditions prior to or at the time of any award, when in the Department's judgment these conditions are necessary to assure or protect advancement of the approved program, the interests of public health, or the proper use of grant funds.

[FR Doc. 80-16733 Filed 6-2-80; 8:45am]
BILLING CODE 4110-84-M

Subpart B - Sterilization of Persons In Federally Assisted Family Planning Projects

Source: 43 FR 52165, Nov. 8, 1978, unless otherwise noted.

§ 50.201 Applicability.

The provisions of this subpart are applicable to programs or projects for health services which are supported in whole or in part by Federal financial assistance, whether by grant or contract, administered by the Public Health Service.

§ 50.202 Definitions.

As used in this subpart:

"Arrange for" means to make arrangements (other than mere referral of an individual to, or the mere making of an appointment for him or her with, another health care provider) for the performance of a medical procedure on an individual by a health care provider other than the program or project.

"Hysterectomy" means a medical procedure or operation for the purpose of removing the uterus.

"Institutionalized individual" means an individual who is (l) involuntarily confined or detained, under a civil or criminal statute, in a correctional or rehabilitative facility, including a mental hospital or other facility for the Care and treatment of mental illness, or (2) confined, under a voluntary commitment in a mental hospital or other facility for the care and treatment of mental illness.

"Mentally incompetent individual" means an individual who has been declared mentally incompetent by a Federal, State, or local court of competent jurisdiction for any purpose unless he or she has been declared competent for purposes which include the ability to consent to sterilization.

"Public Health Service" means the Health Services Administration, Health Resources Administration, National Institutes of Health, Center for Disease Control, Alcohol, Drug Abuse and Mental Health Administration and all of their constituent agencies.

The "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

"Sterilization" means any medical procedure, treatment, or operation for the purpose of rendering an individual permanently incapable of reproducing.

§ 50.203 Sterilization of a mentally competent individual aged 21 or older.

Programs or projects to which this subpart applies shall perform or arrange for the performance of sterilization of an individual only if the following requirements have been met:

(a) The individual is at least 21 years old at the time consent is obtained.

(b) The individual is not a mentally incompetent individual.

(c) The individual has voluntarily given his or her informed consent in accordance with the procedures of Sec. 50.204 of this subpart.

(d) At least 30 days but not more than 180 days have passed between the date of informed consent and the date of the sterilization, except in the case of premature delivery or emergency abdominal surgery. An individual may consent to be sterilized at the time of premature delivery or emergency abdominal surgery, if at least 72 hours have passed after he or she gave informed consent to sterilization. In the case of premature delivery, the informed consent must have been given at least 30 days before the expected date of delivery.

§ 50.204 Informed consent requirement.

Informed consent does not exist unless a consent form is completed voluntarily and in accordance with all the requirements of this section and Sec. 50.205 of this subpart.

(a) A person who obtains informed consent for a sterilization procedure must offer to answer any questions the individual to be sterilized may have concerning the procedure, provide a copy of the consent form, and provide orally all of the following information or advice to the individual who is to be sterilized:

(1) Advice that the individual is free to withhold or withdraw consent to the procedure any time before the sterilization without affecting his or her right to future care or treatment and without loss or withdrawal of any federally funded program benefits to which the individual might be otherwise entitled:

(2) A description of available alternative methods of family planning and birth control;

(3) Advice that the sterilization procedure is considered to be irreversible;

(4) A thorough explanation of the specific sterilization procedure to be performed;

(5) A full description of the discomforts and risks that may accompany or follow the performing of the procedure, including an explanation of the type and possible effects of any anesthetic to be used;

(6) A full description of the benefits or advantages that may be expected as a result of the sterilization; and

(7) Advice that the sterilization will not be performed for at least 30 days except under the circumstances specified in § 50.203(d) of this subpart.

(b) An interpreter must be provided to assist the individual to be sterilized if he or she does not understand the language used on the consent form or the language used by the person obtaining the consent.

(c) Suitable arrangements must be made to insure that the information

specified in paragraph (a) of this section is effectively communicated to any individual to be sterilized who is blind, deaf or otherwise handicapped.

(d) A witness chosen by the individual to be sterilized may be present when consent is obtained.

(e) Informed consent may not be obtained while the individual to be sterilized is:

(1) In labor or childbirth;

(2) Seeking to obtain or obtaining an abortion; or

(3) Under the influence of alcohol or other substances that affect the individual's state of awareness.

(f) Any requirement of State and local law for obtaining consent, except one of spousal consent, must be followed.

§ 50.205 Consent form requirements.

(a) Required consent form. The consent form appended to this subpart or another consent form approved by the Secretary must be used.

(b) Required signatures. The consent form must be signed and dated by:

(1) The individual to be sterilized; and

(2) The interpreter, if one is provided; and

(3) The person who obtains the consent; and

(4) The physician who will perform the sterilization procedure.

(c) Required certifications. (1) The person obtaining the consent must certify by signing the consent form that:

(i) Before the individual to be sterilized signed the consent form, he or she advised the individual to be sterilized that no Federal benefits may be withdrawn because of the decision not to be sterilized,

(ii) He or she explained orally the requirements for informed consent as set forth on the consent form, and

(iii) To the best of his or her knowledge and belief, the individual to be sterilized appeared mentally competent and knowingly and voluntarily consented to be sterilized.

(2) The physician performing the sterilization must certify by signing the consent form, that:

(i) Shortly before the performance of the sterilization, he or she advised the individual to be sterilized that no Federal benefits may be withdrawn because of the decision not to be sterilized

(ii) He or she explained orally the requirements for informed consent as set forth on the consent form, and

(iii) To the best of his or her knowledge and belief, the individual to be sterilized appeared mentally competent and knowingly and voluntarily consented to be sterilized. Except in the case of premature delivery or emergency abdominal surgery, the physician must further certify that at least 30 days have passed between the date of the individual's signature on the consent form and the date upon which the sterilization was performed. If premature delivery occurs or emergency abdominal surgery is required within the 30-day period, the physician must certify that the sterilization was performed less than 30 days but not less than 72 hours after the date of the individual's signature on the consent form because of premature delivery or emergency abdominal surgery, as applicable. In the case of premature delivery the physician must also state the expected date of delivery. In the case of emergency abdominal surgery, the physician must describe the emergency.

(3) If an interpreter is provided, the interpreter must certify that he or she translated the information and advice presented orally, read the consent form and explained its contents and to the best of the interpreter's knowledge and belief, the individual to be sterilized understood what the interpreter told him or her.

§ 50.206 Sterilization of a mentally incompetent individual or of an institutionalized individual.

Programs or projects to which this subpart applies shall not perform or arrange for the performance of a sterilization of any mentally incompetent individual or institutionalized individual.

§ 50.207 Sterilization by hysterectomy.

(a) Programs or projects to which this subpart applies shall not perform or arrange for the performance of any hysterectomy solely for the purpose of rendering an individual permanently incapable of reproducing or where, if there is more than one purpose to the procedure, the hysterectomy would not be performed but for the purpose of rendering the individual permanently incapable of reproducing.

(b) Programs or projects to which this subpart applies may perform or arrange for the performance of a hysterectomy not covered by paragraph (a) of this section only if:

(1) The person who secures the authorization to perform the hysterectomy has informed the individual and her representative, if any, orally and in writing, that the hysterectomy will render her permanently incapable of reproducing; and

(2) The individual or her representative, if any, has signed a written acknowledgment of receipt of that information.

§ 50.208 Program or project requirements.

(a) A program or project must, with respect to any sterilization procedure or hysterectomy it performs or arranges, meet all requirements of this subpart.

(b) The program or project shall maintain sufficient records and documentation to assure compliance with these regulations, and must retain such data for at least 3 years.

(c) The program or project shall submit other reports as required and when requested by the Secretary.

§ 50.209 Use of Federal financial assistance.

(a) Federal financial assistance administered by the Public Health Service may not be used for expenditures for sterilization procedures unless the consent form appended to this section or another form approved by the Secretary is used.

(b) A program or project shall not use Federal financial assistance for any sterilization or hysterectomy without first receiving documentation showing that the requirements of this subpart have been met. Documentation includes consent forms, and acknowledgments of receipt of hysterectomy information.

Attachment D

OFFICES 0F REGIONAL PROGRAM CONSULTANTS (RPC's) FOR FAMILY PLANNING*

DHHS Region	Address	Telephone	States
I	DHHS Region I, JFK Federal Building, Rm. 2126 Boston, MA 02203	(617) 565-1060	CT, ME, MA, NH, RI, VT
II	DHHS Region II, 26 Federal Plaza, Rm. 3337 New York, NY 10007	(212) 264-3935	NJ, NY, Puerto Rico, Virgin Is.
III	DHHS Region III, 150 S. Independence Mall West, Ste. 426, Philadelphia, PA 19106	(215) 861-4641	DE, DC, MD PA, VA, WV
IV	DHHS Region IV, 61 Forsyth St., S.W., Ste. 5B95, Atlanta, GA 30323	(404) 562-7900	AL, FL, GA, KY, MS, NC, SC, TN
V	DHHS Region V, 105 West Adams St., 17th Floor, Chicago, IL 60603	(312) 886-3864	IL, IN, MI, MN, OH, WI
VI	DHHS Region VI, 1301 Young St., Ste. 766 Dallas, TX 75202	(214) 767-3060	AR, LA, NM, OK, TX
VII	DHHS Region VII, Federal Office Building, 601 E. 12th St., Rm. 501, Kansas City, MO 64106	(816) 426-2924	IA, KS, MO, NE
VIII	DHHS Region VIII, 11037 Federal Building, 1961 Stout St., 4th Floor, Denver, CO 80294	(303) 844-6163 x399	CO, MT, ND, SD, UT, WY
IX	DHHS Region IX, 50 United Nations Plaza, San Francisco, CA 94102	(415) 437-8116	AZ., CA, HI, NV, and the Six U.S. Associated Pacific Jurisdictions
X	DHHS Region X, Blanchard Plaza, 2201 Sixth Ave., M/S RX-29, Seattle, WA 98121	(206) 615-2501	AK, ID, OR, WA

*Updated July 1999

Attachment E

APPENDICES

Part I

6.4 Facilities and Accessibility of Services

- Ambulatory Health Care Standards (BCHS, 1977)

  Available from the Regional Offices or BCHS

6.7 Reporting Requirements

- Instruction Manual for the BCHS Common ReportjnZ Requirements (SCHS, 1980; Revised periodically)

  Available from the Regional Offices or BCHS

6.8 Indicators for Funding

- Funding Criteria for BCHS Programs (BCHS; Revised periodically)

  Available from the Regional Offices or BCHS

Part II

8.4 Fertility Regulation

Temporary Contraception

- Natural Family Planning Services (BCHS Regional Memorandum, 79-12)

  Available from the Regional Offices or BCHS

Permanent Contraception

- Understanding Female Sterilization (DHHS, 1976)
- A Male Sterilization Procedure (DHHS, 1976)
- Your Sterilization Operation: Information for Women (DHHS, 1978), also available in Spanish
- Your Sterilization Operation: Information for Alen (-DHHS, 1978, also available in Spanish

  Available from the NEtional Clearinghouse for Family Planning Information

8.5 Infertility Services

- Handbook on Infertilitv Services (BCHS, 1981)*

8.7 Adolescent Services

- Adolescent Health Care: A Guide for BCHS-Supported Programs and Projects (BCHS, 1979)
- Counseling, Adolescents in Reproductive Health Care Settings (BCHS, 1980)

  Available from the Regional Offices or BCHS

8.8 Sexually Transmitted Diseases

- Diagnosis and Treatment of Sexually Transmitted Diseases in Fami]y -Planning Projects (BCHS, 1981)*

8.9 Estrogen-Exposed Offspring

- Physician Advisor : Health effects of the Pregnancy Use of Diethylstilbestrol (October 4, 1978)

  Available from the Office of the Assistant Secretary for
  Health, U.S. Department of Health and Human Services,
  Washington, D.C. 20201

9.3 Genetic Screening

- Clinical Genetic Service Centers: A National Listing, (DHHS, 1980)

  Available from the National Clearinghouse for Family Planning Information

9.4 Health Prom ot ion/Disease Prevention

- Health Promotion: An Assessment for BCHS Projects (BCHS, 1981)
- Health Promotion and Disease Prevention in a Reproductive Health Care Setting (BCHS, 1981)*
- Nutrition Service Guide for Family Planning Projects (BCHS, 1981).

Attachment F

RELATED DOCUMENTS

Part I

6.2 Planning and Evaluation

- Family Planning Project Evaluation Protocol (BCHS, 1978)

Available from the Regional Offices or BCHS

8.4 Fertility Regulation

Temporary Contraception

- Hatcher RA, et al: Contraceptive Technology . New York, Irvington Publishers, 1980
- Porter CW Jr., et al: Oral Contraceptives: A Guide for Programs and Clinics. Third edition. Chestnut Hill, MA, Pathfinder, 1979
- Oral Contraceptives. Population Reports, Series A. No. January, 1979
- Second Report on Intrauterine Contraceptive Devices. Food and Drug Administration, December, 1978
- Intrauterine Devices. Population Reports, Series B, No. 3, May, 1979

Permanent Contraception

- Penfield AJ: Female Sterilization by Minilaparotomy or Open Laparoscopy. Baltimore, Urban & Schwarzenburg, 1980
- Sciarra JJ, et al: Control of Male Fertilitv. New York, Harper &- Row, 1975

10.1 Prenatal Care

Maternitv Services

- Standards for Obstetric-Gynecologic Services. Chicago, The American College of Obstetricians and Gynecologists, 1974, 1981*

10.1 Prenatal Care

Maternity Services

- Guidance for Maternity Services in BCHS Programs and Projects (BCHS, 1981)*

10.2 Postpartum Care

Maternity Services

- Guidance for Maternity Services in BCHS Program and Projects (BCHS, 1981)*

11.3 Medical Records

- Problem-Oriented Medical Record System and Medical Record Management Guidance (BCHS, 1978)

Available from the Regional Offices or BCHS

11.4 Quality Assurance

- Primary Care Effectiveness: An Approach to Quality Assurance in BCHS Programs and Projects (BCHS, 1980)

Available from the Regional Offices or BCHS

- Publications not yet available.

10.2 Postpartum Care

Maternity Services

- Standards for Obstetric-Gynecologic Services. Chicago, The American College of Obstetricians and Gynecologists, 1974, 1981*

Available from The American College of Obstetricians and Gynecologists, 600 Maryland Avenue, S.W., Suite 300, Washington, D.C. 20024

11.4 Quality Assurance

- Patient Care Audit Manual (PPFA, 1980) -

Available from Planned Parenthood Federation of America, 810 Seventh Avenue, New York, NY 10019

DHHS CENTRAL OFFICE*

U.S. Department of Health and Human Services
Office of Public Health and Science
Office of Population Affairs
Office of Family Planning
4350 East West Hwy., Suite 200 West
Bethesda, MD 20814

OTHER SOURCES OF
FAMILY PLANNING INFORMATION*

Superintendent of Documents
U.S. Government Printing office
Washington, D.C. 20402

Office of Population Affairs Clearinghouse
P.O. Box 30686
Bethesda, MD 20824-0686
(301) 654-6190
FAX: (301) 215-7731

*Updated July 1999

FAMILY PLANNING GENERAL TRAINING GRANTEES (1980-1981)*

DHHS Region	Address	Telephone	States
I	JSI Research and Training Institute, Inc., 210 Lincoln St., 6th Fl., Boston, MA 02111	(617) 482-9485	CT, ME., MA., NH RI, VT
II	Cicatelli Associates, Inc, 505 8th Ave., Suite 2001, New York, NY 10018	(212) 594-7741	NJ, NY, Puerto Rico, Virgin Is.
III	Family Planning Council of Southeastern Pennsylvania, 260 Broad Street, Ste. 1900, Philadelphia, PA 19102	(215) 985-2640	DE, DC, MD PA, VA, WV
IV	Emory University, United Way Building, Rm. 802, 100 Edgewood Ave., N.E., Atlanta. GA 30303	(404) 523-1996	AL, FL, GA, KY MS, NC, SC, TN
V	Planned Parenthood of Wisconsin, Inc. 302 North Jackson Street Milwaukee, WI 53202-5917	(414) 271-8045	IL, IN, MI, MN, OH, WI
VI	Center for Health Training, 421 East 6th Street, Ste. B, Austin, TX 78701	(512) 474-2166	AR, LA, NM, OK, TX
VII	Development Systems, Inc., 3100 Main Street Ste. 100, Kansas City, MO 64108	(816) 561-5050	IA, KS, MO, NE
VIII	JSI Research and Training Institute 1738 Wynkoop Street, Ste. 201, Denver, CO 80202	(303) 293-2405	CO, MT, ND, SD, UT, WY
IX	Center for Health Training, 2229 Lombard St., Son Francisco, CA 94123	(415) 929-9100	AZ., CA, HI, NV, and the Six U.S. Associated Pacific Jurisdictions
X	Center for Health Training, 400 Tower Building, 1809 Seventh Avenue, Seattle, WA 98101	(206) 447-9538	AK, ID, OR, WA

*Updated July 1999